

BIA policy paper

A call to action: Driving deep biotech through policy

BIA policy recommendations to realise the full potential of UK deep biotech – disruptive innovation for global sustainability

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Introduction

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

BIA has coined the term Deep Biotech to refer to the subsector of the biotech industry that encompasses innovative companies powered by engineering biology that address humanity's greatest challenges beyond health, such as environmental pollution and waste, food security, and the climate crisis. These innovative companies are key to the UK's mission to kickstart economic growth while accelerating our path to net zero at the same time.

The benefits of this sector are significant, as showcased in the BIA's 2024 <u>Deep Biotech report</u>. UK deep biotech companies use the power of biology to protect crops and help ensure food security, create sources of energy without the need for fossil fuels, make textiles and packaging from enzymes instead of harmful petrochemicals or resource-intensive cotton, cultivate meat without farming animals, and develop enzymes to turn plastic waste into everyday chemicals. Together, these companies are creating the innovations today that will form the backbone of our bioeconomy tomorrow.

The UK is not alone in pursuing the path towards a sustainable bioeconomy. In September 2022, President Biden signed an Executive Order aiming to catalyse the growth of the US bioeconomy, which resulted in the 2023 <u>Bold Goals for U.S. Biotechnology and Biomanufacturing</u>. The 2020 European Green Deal set out the EU's path to a green transition and was followed by the EU's 2024 Biotech and Biomanufacturing Initiative. The EU is now looking at a 2025 Biotech Act. Japan published a <u>Bioeconomy Strategy</u> in 2024. The UK Government has published a <u>National Vision for Engineering Biology</u> in 2023 which sets out the Government's plan to harness the power of biology to deliver new medical therapies, crop varieties, eco-friendly fuels and chemicals, and increased resilience of supply chains.

In close consultation with our Deep Biotech membership, and in collaboration with organisations aligned with BIA's mission, we have identified three key areas – **regulation**, **finance**, and **infrastructure** – where policy levers are needed to further the success of Deep Biotech in the UK. This paper then puts these recommendations in context of the Labour Government's missions and

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industrial strategy, current Government policy, and in the international context.

Recommendations

It is vital for the UK to ensure that innovative companies can access the necessary infrastructure and finance and have a clear regulatory pathway if the UK wants deep biotech to scale and succeed in the UK. The below recommendations on **regulation**, **finance**, and **infrastructure** indicate what public policy levers and Government support are needed to make significant progress for UK deep biotech.

1. Better regulation

R.1 Improve regulatory clarity for deep biotech products and processes

While for some companies the regulatory pathway and/or regulator is clear, this is not the case across engineering biology applications. Innovation in engineering biology is outpacing existing regulatory frameworks, creating significant gaps. Working together, with public research funders and with industry, regulators must ensure that where regulation is required for innovative products, it is provided, and where it is not, it is clear that companies can commercialise their products and reach market safe in the knowledge that they are acting within UK law. This includes:

- 1) publishing an overview of regulatory bodies and pathways for engineering biology-based products, including information on how innovative engineering biology companies can approach regulators and who to approach, through clear signposting and by providing guidance (including case studies) where none exists;
- 2) in line with considerations for biosecurity and responsible innovation, reviewing and updating relevant legislation and regulation to make it fit-for-purpose and future-proof to allow for engineering biology innovations to safely reach market in the UK.

R.2 Resource UK regulators appropriately, both in terms of funding and knowledge

We need regulators to have a pro-innovation, collaborative mindset and to be resourced appropriately, to be able to horizon scan and deliver effective regulation and guidance to deep biotech companies. Regulators must have adequate funding and knowledge to be able to stay

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ahead of the curve, be consistent in their delivery, and provide clear and timely approvals processes, information, and guidance to companies. Regulators must be resourced to build an adequate knowledge base to be able to appropriately and quickly understand and, where relevant, regulate engineering biology innovations. Creating a strong regulatory knowledge base should be done with support from, and in close collaboration with, industry partners, and include early and informal engagement with start-ups and SMEs (see **R.3**).

R.3 Strengthen regulator-industry relationships to build future-proof, enabling regulation to bring novel products to market

Regulators need to increase active and early engagement with early-stage companies and SMEs, prior to applications being filed. This can be materialised through workshops and working groups, facilitated and informal meet ups with companies of similar products and relevant regulators, proactive engagement with industry through the Engineering Biology Regulator's Network (EBRN), and through regulatory sandboxes in areas of most pressing need. The Engineering Biology Sandbox Fund must be continued and built upon to accelerate pro-innovation regulatory reform and encourage deep biotech innovation and investment in the long-term. Strong regulator-industry relationships will further support the regulatory knowledge base (see **R.2**).

R.4 Deploy the Regulatory Innovation Office (RIO) to foster a joined-up approach to Deep Biotech regulation

The new Regulatory Innovation Office (RIO) needs to rapidly, and to scale, deliver on its 'capability' workstream to build capability across the whole regulatory system so it can respond to engineering biology as an emerging technology. This includes using its function to improve regulatory clarity for deep biotech (see **R.1**) and build up UK regulator's knowledge base (see **R.2**). The RIO needs to work closely with the Regulatory Horizons Council (RHC) and the Engineering Biology Regulator's Network (EBRN) so not to duplicate efforts but make targeted interventions to drive pro-innovation regulation in deep biotech. The RIO should develop advice for regulatory bodies to assess the most pressing regulatory gaps and improve regulatory clarity for deep biotech companies (see **R.1**), as well as serve as a single front door for those innovations that have no currently identified regulatory pathway and/or regulator. The regulatory bodies to engage with include, but are not limited to, the OPSS, HSE, DEFRA, FSA, EA, APHA, HMRC, MHRA, HMRC and CAA.

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R.5 Create a regulatory framework that is globally competitive and attractive

Ajoined-up approach to deep biotech regulation in the UK (see **R.4**) must not only lead to regulatory clarity and an improved regulatory process for deep biotech companies (see **R.1**), but must ensure that the UK's regulatory framework for deep biotech is globally competitive with key markets (incl. the EU and US) and attractive to companies and investors. Close attention must also be paid to the benefits of regulatory convergence (e.g. EU & UK REACH) vs divergence (e.g. Genetic Technologies (Precision Breeding)) with key markets. A strong and supportive regulatory environment has a crowding-in effect, signalling to companies and investors alike to stay and grow here, and enabling companies to launch their products in the UK to the benefit of the UK's society, environment, and economy. In addition, we need UK regulators to work with international counterparts in key countries, including through mutual recognition agreements or MoUs and development and recognition of standards, to improve regulatory approvals and aid with opening markets to engineering biology companies.

2. Better access to Finance

F.1 Provide ringfenced public funding for deep biotech through Innovate UK

We need a pipeline of public funding interventions, particularly grants, awards and challenge funds, across different stages of companies' development, with a clear path to funding available from proof of concept to scale-up and clear timeline of funding available over multiple years, which may vary across different sector applications of deep biotech. Importantly, we need Innovate UK funds that are ringfenced for engineering biology application areas across sectors and not in competition for funding with other technologies. In addition, private investors need to be brought in early through investor partnerships linked to public funding programmes. This will lead to a strong funding and financing path for deep biotech companies, and will crowd in corporate venture capital.

F.2 Ensure deep biotech SMEs benefit from the research-intensive R&D tax relief rate

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Like most life sciences and biotech SMEs, deep biotech companies are characterised by their focus on R&D and innovation. Deep biotech SMEs must benefit from the UK's research-intensive R&D tax relief regime.

F.3 Establish an engineering biology focused team within British Patient Capital (BPC)

British Patient Capital (BPC) should focus on R&D intensive businesses, grow their expertise in engineering biology, and fund deep biotech. BPC needs a greater focus on engineering biology as a priority area for the UK and to match the focus given to deep biotech by the National Vision for Engineering Biology and the new Regulatory Innovation Office (RIO), by establishing a dedicated engineering biology stream and team. Currently, the sector tends to fall between deep tech and life science teams, and may not be getting the focus it needs. This should be integrated with both BPC and the new British Growth Partnership, allowing deep biotech companies to also benefit from investment unlocked from the UK pensions industry as part of the Mansion House Reforms.

F.4 Introduce financial and tax incentives to drive investment into and uptake of deep biotech

Financial policy levers need to be deployed that will increase investment into deep biotech, including attracting key investment from abroad, drive demand and create market pull. The government must continue to implement the Mansion House Reforms to unlock capital that is key to delivering long-term strength in the UK venture financing ecosystem that most engineering biology companies rely on. The Government should explore procurement levers, such as modelled on the US' BioPreferred program, and with both government as a guaranteed customer and providing purchase order financing. Tax incentives such as rebates for biosolutions and for the use of engineering biology-based products and processes can create market pull and encourage uptake of such products, and incentivises corporate investment. This includes tax credits for sustainable biomanufacturing.

3. Better access to Infrastructure

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'Infrastructure' refers to physical infrastructure, both for upstream and downstream processing, including pilot and scale up bioprocessing/fermentation facilities and specialist equipment, as well as analytics. These are needed during both R&D and commercial stages of a company's development.

I.1 Increase accessibility of infrastructure for SMEs

Both to start and to reach scale, deep biotech SMEs need costly and/or large physical infrastructure and specialist equipment. Existing pilot and scale-up infrastructure/facilities need to be made more accessible through better information (see **1.2**) and financial (see **1.3**) levers. Smart sharing of existing infrastructure needs to be enabled, and universities and other infrastructure holders should be encouraged and supported to share their facilities and make it easier for companies to enter agreements and negotiate rapid access.

1.2 Improve information around availability of open-access infrastructure

Exhaustive information about all open-access facilities, as well as private or other facilities that are available to access and use by SMEs, should be made publicly available. This includes information on location, capabilities and equipment, capacities, etc. A thorough analysis on the availability of open access infrastructure in the UK and the specific needs of the UK's deep biotech start-ups and SMEs is needed for better demand and supply signalling between SMEs and infrastructure providers. This can be enabled and disseminated through publicly available databases such as pilots4u. This will further determine the need for large-scale investment into the types of new infrastructure that the UK may be lacking (see 1.4). In addition, we need faster processes for obtaining permits by companies who look to build scale-up infrastructure themselves.

1.3 Provide public funding support to increase the affordability of existing infrastructure

Companies need funding support to access existing pilot and scale-up facilities in a cost-accessible way, including for upstream and downstream bioprocessing, and to access specialist equipment, noting that different sectors need different equipment. Funding support is also needed for the continued running of existing facilities and the staff needed to support companies throughout the process. A voucher or credit scheme, managed by IUK or an independent body, for companies to

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spend at vetted facilities could be trialled to support companies, and to stimulate demand and increase capacity in the system of infrastructure providers. The size of such vouchers or credits must cover the cost of access to and use of facilities for a given project. Lastly, such funding mechanisms should take into account diverging needs in accessing infrastructure for established or standard scale-up techniques, versus entirely novel techniques.

I.4 Invest in UK-based scale-up infrastructure and skills to meet demand of SMEs

Government should invest in UK-based infrastructure where existing provision is identified as lacking or difficult to access by UK companies (see **I.1** and **2**) including, but not limited to, large-scale food-grade fermentation facilities for cultivated novel foods. Such investment will de-risk and incentivise private investment into start-ups that otherwise could not generate proof of concept for their potential products, and enable them to scale in the UK. It also must include financing of the highly skilled staff that are essential to running and maintaining such infrastructure and equipment. A sustainable pipeline of talent with technical skills must be supported, aided by sustainable immigration policies.

Recommendations in context of Labour's mission-driven government and Industrial Strategy

UK deep biotech is uniquely well-placed to support the Labour Government's missions. Deep biotech not only drives *economic growth* but does so while accelerating our path to *net zero* and providing *high-quality jobs*. Its revolutionary power allows us to harness biological innovation to live more harmoniously with nature while transforming traditional industries and creating new ones for the benefit of the economy, society, and our environment.

In 2020, McKinsey <u>estimated</u> that the 'direct annual global impact of the biorevolution could be \$2 trillion to \$4 trillion in 2030-40'. The potential of deep biotech to help reach our net zero and sustainability goals, and to create a truly sustainable bioeconomy, is enormous. The UK is already a world leader in engineering biology R&D and has a burgeoning start-up and SME base. The UK is leading Europe in the number of biotech startups and funding for those companies over 2017 to 2022. UK engineering biology firms, including those in the health sector, have <u>fundraised</u> over £5.2 billion between 2017 to 2022, ranking third globally only behind the US and China.

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Its cross-cutting nature means that deep biotech can provide solutions that support as many as 10 out of 17 Sustainable Development Goals (SDGs). In agriculture, deep biotech companies are ushering in an era of food security by providing us with novel sustainable proteins or agri-chemicals. Novel materials derived from proteins or biobased hydrocarbons are changing our relationship with traditional fabrics and packaging. New processes, enabled by enzymes and microorganisms, are allowing use to recycle and clean up pollution in a way that works with nature instead of against it. And biofuels are delinking carbon intensive industries like transport and shipping from fossil fuels.

It is estimated that more than half of the economic impact from applications of biotechnology overall will lie outside healthcare - in 2014, the bioeconomy overall was <u>estimated</u> to contribute £220 billion GVA to the UK economy and supporting over five million jobs. Added to this, employment growth in the wider UK industrial biotechnology sector has <u>outpaced</u> national averages, increasing by more than 10% per year, with median earnings around £20,000 above the national average.

Deep biotech provides a unique opportunity to Labour's missions, and can positively transform at least five of the eight growth-driving sectors identified in the industrial strategy green paper, including digital and technologies, advanced manufacturing, clean energy industries, defence, and life sciences. Engineering biology is one of the UK's unique strengths and untapped potential, enabling the UK's world-leading sectors to adapt and grow, and seizing opportunities to lead in new sectors, with high-quality, well-paid jobs. The recommendations listed in this paper therefore must be realised through the UK's industrial strategy and across relevant Sector Plans for a joint-up approach to realising deep biotech's contribution to the UK economy, society, and the environment.

Find out more about the role of deep biotech and engineering biology in the UK's industrial <u>strategy</u>

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Recommendations in context of UK Government policy

The 2023 <u>Vision</u> that the new Labour Government has re-committed to in 2024, was received well by industry, and it is important that Government continue to work closely with industry to implement it.

The Vision provides a strong signal of intent from Government, showing that engineering biology and deep biotech are a priority. However, while it sets out £2 billion of investment into engineering biology over 10 years, BIA are aware this is not new money but reflects the approximate spend on UK engineering biology across all departments and areas of the last 10 years. It therefore is not ambitious enough given the breadth and impact of engineering biology, and the rising costs associated with research and attracting talent. Further investment is needed to meet the Vision's ambitions and those of the UK's modern industrial strategy.

Engineering biology in the economy, Regulations and Standards, and Infrastructure have rightly been identified in the Vision as three of the six priority areas where challenges and opportunities exist to create a broad and rich engineering biology ecosystem. The 2025 House of Lords Science & Technology Committee report 'Don't fail to scale: seizing the opportunity of engineering biology' further cemented this position, drawing out infrastructure, regulation and investment as policy areas that the UK 'must get right' for a flourishing UK engineering biology sector. Significant progress must be made in, and funding channelled into, these three areas in the first half of the 10-year Vision in order to ensure innovative companies can succeed and scale, and future start-ups are welcomed by a supportive, globally competitive UK ecosystem in which they can thrive. Below we set out how our recommendations can be applied to the Vision's priority areas:

Engineering biology in the economy

In the Vision, the Government sets out principles to tackle barriers to economic growth, one of which was lack of private investment. The Mansion House reforms that channel capital from pension funds into innovative growing businesses have been welcomed by industry, and Government must continue to implement them (**F.4**), however there is much more that can be done to drive investment into deep biotech. Financial policy levers need to be deployed to drive demand and create market pull (**F.4**). This will create investor confidence in the commercial potential of deep

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biotech. In order to pull firms' innovations through to adoption by customers, Government should go further than building the profile of engineering biology amongst its departments, by establishing an engineering biology focused team within British Patient Capital (BPC) (**F.3**) on one hand, and by using procurement levers, following the example of the US' BioPreferred program, and tax and other incentives (**F.2**) for developing, manufacturing and buying deep biotech products (**F.4**), on the other.

• Regulations and Standards

Industry and Government are in agreement that the UK needs a clear and supportive regulatory landscape that makes the country an attractive place to bring innovative products to market, while maintaining high consumer safety standards. The Vision set the Engineering Biology Regulator's Network (EBRN) the task of publishing a map of sector specific regulatory pathways for engineering biology products, to make it easier for industry to navigate the regulatory system. Industry would value signposting, clear guidance, case studies, and the opportunity to engage with key regulatory stakeholders. The mapping take this account (**R.1**). exercise must into

The Vision seeks to reform the regulatory environment, and the underpinning legislation where needed, based on research by the Regulatory Horizons Council (RHC) to identify specific regulatory challenges. Industry would welcome this reform and ask that any reforms to legislation or regulation be future-proof to ensure that novel and disruptive innovations are actively enabled by the regulatory system (R.1 and R.3). It is key that the Regulatory Innovation Office (RIO), the RHC and the EBRN work together along with stakeholders from across government departments, and the full spectrum of regulators, to ensure a joined-up approach to regulation across all sectors of deep biotech (R.1 and R.4).

In order to create a progressive regulatory framework equipped with engineering biology expertise, regulators need to be adequately resourced in terms of funding and knowledge, and more focus needs to be placed on building connections with the engineering biology industry, so that any reforms can be co-created with innovators, based on an understanding of the products they are developing (R.3). The Engineering Biology Sandbox Fund is a welcome first step, but engagement needs to take multiple forms to accelerate progress across the gamut of engineering biology products (R.3 and R.4).

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The Vision seeks to learn from and implement global regulatory best practice. Industry supports these efforts and would further suggest that it is essential to consider the impact of regulatory convergence vs divergence with key markets in order to make the UK's regulatory environment globally competitive and attractive (R.5).

Infrastructure

The Vision identified that gaps in infrastructure are a key challenge for deep biotech companies. It sets out the goal of reducing the costs of both the early stages of engineering biology innovation, and its scale-up by providing UK infrastructure.

In order to make existing facilities more relevant, accessible and discoverable, smart sharing of existing infrastructure needs to be enabled (I.1), and a systematic approach needs to be taken to improve information around availability of open-access infrastructure (I.2). Any forthcoming plans to ameliorate the UK's infrastructure capabilities should be based on an exhaustive map of open access facilities, and those facilities which could be made available for use by deep biotech companies (I.2).

Affordability is a key issue for SMEs who need to access infrastructure. In the Vision, the Government committed to exploring the range of public and private funding models that could increase accessibility. Public funding models such as a voucher or credit scheme for companies to spend with vetted infrastructure providers would make existing infrastructure more affordable and reduce the need for companies to access facilities abroad (1.3).

The Vision seeks to build sufficient domestic expertise and capability available to keep firms rooted in the UK even as they expand into global markets. In order to achieve this, the Government needs to invest in UK-based scale-up infrastructure to meet the demand of SMEs (I.4). Crucially, any efforts to increase UK infrastructure capability should be matched with funding for infrastructure providers to maintain facilities and retain highly skilled staff (I.3 and I.4). This needs to be reinforced by a sustainable pipeline of talent with technical skills, with both the education and immigration routes considered and supported (I.4).

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Recommendations in the international context

The UK's engineering biology companies operate in a globally connected and competitive landscape, with investment highly mobile. Unless the ambitions of European and international policy initiatives are matched by the UK, there is a risk of the UK falling behind and missing out on the true potential of deep biotech and engineering biology, an area the UK currently shows significant strengths in globally. Policy initiatives have a crowding-in effect, signalling to companies and investors alike to stay and invest. Modern and advanced regulatory systems attract companies to launch their products in those jurisdictions, and access to infrastructure and affordable scale-up facilities and manufacturing capacities incentivises companies to grow there.

What BIA will do

Over the coming months and years, BIA will work with industry, Government and parliamentarians, and other stakeholders to delve deeper into and drive the implementation of those recommendations. Those activities will be supported by our expert Engineering Biology Advisory Committee (EBAC) and our growing deep biotech Community through which we will ensure our members' voice is heard on matters that are critical to deep biotech's success. We will provide the industry voice to the implementation of the recent recommendations of the House of Lords Science & Technology Committee report on engineering biology and the recommendations of the Regulatory Horizons Council report on the governance of engineering biology.

We will connect the UK's deep biotech and engineering biology ecosystem through industry-leading events and expert groups, and showcase the sector's contributions to a global sustainable bioeconomy. We will produce evidence-led reports and online content highlighting those contributions and their importance.

Find out more about how to get involved

Looking further afield, the BIA is expanding its global reach to key partners including in Europe, the US and Japan. BIA is part of EuropaBio, as well as the <u>European Biosolutions Coalition</u>, an initiative established in October 2023 and consisting of eleven industry organisations from across the European continent. As part of the Coalition, BIA are dedicated to the green transition,

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strengthening the UK and Europe, and creating lasting difference on the European continent and the world through biosolutions.

Read more about the Coalition and its recommendations in the Manifest: <u>How Biosolutions can strengthen Europe's sustainability, resilience and competitiveness.</u>

About the BIA

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world changing innovation. Our members include start-ups, biotechnology and innovative life science companies, large pharmaceutical companies, universities, research centres, tech transfer offices, incubators and accelerators, and a wide range of life science service providers: investors, lawyers, IP consultants, and IR agencies. We promote an ecosystem that enables innovative biotech companies to start and grow successfully and sustainably.

Get in touch!

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